REMARKS

Applicant respectfully requests reconsideration in view of the following remarks.

Introduction-Claim Status

The Office Action indicates that claims 1-21 are pending, and claims 13-21 are withdrawn from consideration. Of the pending claims under consideration, claims 1, 9, and 10 are in independent form.

Applicants gratefully acknowledge the withdrawal of the previous rejection of claims 1-12 under 35 USC 103(a) as being unpatentable over Lillig et al. (US 4,965,049) in view of Groth et al. (US 5,690,103) and in further view of Furlong et al. (Clinical Chemistry, 1990).

The 35 U.S.C. §112, ¶2 Rejections

Claims 1-12 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office Action identifies the language "wherein the hierarchical decision-tree organization includes at least a plurality of paths of the biochemical marker measurement steps" as unclear, rendering the claims vague and indefinite. The Office Action further states that it is further unclear as recited what effectively determines these plurality of paths so as to require one measurement type in one instance and not another instance.

Applicant respectfully traverses this rejection on the grounds that in light

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of the specification the ordinarily skilled artisan understands the scope and meaning of

the claims, including the above-quoted claim recitation. As noted in Applicants'

Amendment filed 1/10/03, the above-quoted language is part of a recitation added by

amendment to independent claims 1, 9, and 10 to additionally clarify the meaning of

"reflex algorithm", consonant with Applicants' specification. Specifically, these claims

include the following recitation:

> the reflex algorithm represents a hierarchical decision-tree organization of biochemical marker measurement steps, each of the biochemical marker measurement steps specifying a measurement set comprising at least one immunoassay measurement or at least one clinical chemistry measurement or at least one immunoassay and at least one clinical chemistry measurement, wherein at least two of the biochemical marker measurement steps specify non-identical measurement sets, and wherein the hierarchical decision-tree organization includes at least a plurality of paths of the biochemical marker measurement steps wherein at least one of the plurality of paths of biochemical marker measurement steps includes an immunoassay type and/or a clinical chemistry measurement type not required by another of said plurality of paths of the biochemical marker measurement steps

Applicants respectfully submit that by the ordinary and accustomed

meaning of this claim language itself, each biochemical marker measurement step is

plainly understood by the ordinarily skilled artisan as being one of the steps that are

hierarchically organized as a decision tree. Said differently, each of these steps is

understood as a node of the decision tree, each node "specifying a measurement set

comprising at least one immunoassay measurement or at least one clinical chemistry

measurement or at least one immunoassay and at least one clinical chemistry

measurement". Moreover, those skilled in the art clearly understand from the plain language meaning of "reflex algorithm" and "hierarchical decision-tree organization" that subsequent "nodes" (i.e., "biochemical marker measurement steps") in such decision tree are selectively executed based on the outcome of measurements in a precedent "node".

The specification is also fully consistent with the ordinary meaning of this claim language. For example, as shown for the disclosed embodiment directed to an AMI reflex algorithm, nodes (branching points) in the hierarchical decision tree are associated with predetermined, specified immunoassay(s) measurement(s) and/or clinical chemistry measurement(s), and a given subsequent "node" is selectively executed according to the outcomes of the measurements at a precedent node.

Accordingly, as understood by those skilled in the art in view of the claim language itself, as well as in light of the specification, in a reflex algorithm (i.e., a hierarchical decision tree organization of specified measurement steps) the results of a given measurement step (i.e., the results from one or more biochemical marker measurements carried out at a given step in the algorithm) determine the selection of a subsequent measurement step, the reflex algorithm thus having different possible pathways ("paths") for traversing the measurement nodes in the decision tree. Applicants respectfully submit that this claim recitation, therefore, plainly recites and elaborates what is known to those skilled in the art as a "reflex algorithm".

For at least the foregoing reasons, Applicants respectfully submit that in light of the specification the scope and meaning of claims 1-12 is clear and definite to

one skilled in the art, and thus, this rejection should be withdrawn.

The 35 U.S.C. §112, ¶1 Rejections – Written Description

The Office Action rejects claims 1-12 under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Office Action asserts that the specification does not appear to provide literal or descriptive support for the recitation of "reflex algorithm . . . represents a hierarchical decision-tree organization of biochemical marker measurement steps, each of the biochemical marker measurement steps specifying a measurement set comprising . . . wherein at least two of the biochemical marker measurement steps specify non-identical measurement sets, and wherein the hierarchical decision-tree organization includes at least a plurality of paths of the biochemical marker measurement steps wherein at least one of the plurality of paths of biochemical marker measurement steps includes an immunoassay type and/or a clinical chemistry measurement type not required by another of said plurality of paths of the biochemical marker measurement steps". Applicants respectfully traverse this rejection on the grounds that the specification reasonably conveys to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

First, Applicants respectfully refer the Examiner to the discussion above

concerning this recitation vis-a-vis the § 112, ¶2 rejection. In view of the above discussion, Applicants respectfully note that this recitation simply and clearly sets forth the meaning of "reflex algorithm" as clearly described throughout the specification.

Additionally, regarding a sequence of biochemical marker measurement steps "wherein at least one of the plurality of paths of biochemical marker measurement steps includes an immunoassay measurement *type* and/or clinical chemistry measurement *type* not required by another of said plurality of paths of the biochemical marker measurement steps", as may be appreciated, this aspect of a "reflex algorithm" as claimed means that at least one of the paths in the hierarchical decision-tree does not require performing at least one distinct measurement type that is required by another path. More specifically, as explained for example in Applicants' specification at page 23 et seq., a feature of Applicants' invention is that it may eliminate the need to perform additional and distinct biochemical marker tests (e.g., distinct assays that may be unnecessary for providing a diagnosis or indication of pathology), thus providing for, *inter alia*, cost reductions (e.g., in the example given in the specification, a path requires myoglobin and total CK but neither CKMB nor cTNI measurements, while another path requires myoglobin, total CK and CKMB but does not require any cTNI measurements, while (as a further example) another path requires myoglobin, total CK, CKMB and cTNI).

For at least the foregoing reasons, Applicants respectfully submit that the above-quoted recitation is clearly supported by the specification, and further that it does not, therefore, constitute new matter. Accordingly, Applicants submit that the §112, ¶1

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rejection based on the written description requirement should be withdrawn.

The 35 U.S.C. §112, ¶1 Rejections – Scope of Enablement

The Office Action rejects claims 1-12 under 35 USC 112, first paragraph, based on the assertion that the specification, while being enabling for reflex algorithm testing for AMI using biochemical markers to diagnose AMI, does not reasonably provide enablement for reflex algorithm testing of any other biochemical markers for diagnosis of any pathology such as parasitic infection or viral infection or cancer. That is, the Office Action asserts that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. More specifically, in making this rejection, the Examiner considers the factors set forth in *In re Wands*, 8 USPQ2d 1400. Applicants respectfully traverse this rejection.

Applicants respectfully submit that the specification clearly and completely describes the invention such that an ordinarily skilled artisan would know how to make and/or use the claimed invention without undue experimentation, and that the enablement of the invention is commensurate with the claim scope, which is not limited to a system that implements only an AMI reflex algorithm. That is, an ordinarily skilled artisan would know how to make and use Applicant's claimed invention (e.g., the apparatus of claim 1) such that the program would implement any reflex algorithm that may be developed and which includes both immunoassays and clinical chemistry assays to diagnose pathology. To limit the scope of Applicant's claimed diagnostic system (e.g,, that includes, *inter alia*, an immunoassay analyzer integrated with a

clinical chemistry analyzer under control of a reflex algorithm) to only systems that implement reflex algorithms expressly disclosed in the specification (or that are already known in the art) unduly and improperly limits Applicant's claimed invention.

Indeed, Applicants are not required to describe every conceivable and possible future embodiment of the invention. *Rexnord Corp. v. Laitram Corp.*, 60 USPQ 2d, 1851, 1856 (Fed. Cir. 2001). Applicants recognize that Examiner's reasoning appears to acknowledge this doctrine insofar as it states that *"While it is not necessary to show working examples for every possible embodiment*, there should be sufficient teachings in the specification that would suggest to the skilled artisan that the breadth of the claimed method is enabled." (Italics and underlining added). This reasoning, however, focuses on a method claim *per* se and does not directly address an apparatus as claimed by Applicant in which a method (namely, a reflex algorithm) delimits a structural element of the claimed combination of elements. The scope of the claimed apparatus should not be limited by the specific reflex algorithm(s) disclosed in the specification. *Cf. SRI Int'l v. Matsushita Elec. Corp of America*, 227 USPQ 577,585 (Fed. Cir. 1985) (en banc) ("[I]f structural claims were to be limited to devices operated precisely as a specification-described embodiment is operated, there would be no need for claims. Nor could an applicant, regardless of the prior art, claim more broadly than that embodiment."),

Moreover, Applicant respectfully submits that implementing the Applicant's system as claimed, but using other to-be-developed reflex algorithms, would not necessarily require undue experimentation. Additionally, that which may appear

"unpredictable" today, may not remain "unpredictable". Thus, it is clearly improper to limit Applicants' claim scope to only the disclosed AMI reflex algorithms.

Accordingly, for at least the foregoing reasons, Applicants submit that the specification clearly enables the invention in a manner commensurate with the claim scope, and thus request withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

The 35 U.S.C. §103(a) Rejections

The Office Action also rejects claims 1-12 under 35 USC 103(a) as being unpatentable over Lillig et al. (US 4,965,049) in view of Cantantore et al. (US 5,772,963) and in further view of Aziz et al. (Journal of Cellular Biochemistry, Supp. 17G, pp. 247 (1993)).

Applicants respectfully traverse this rejection at least because Cantantore et al. does not qualify as prior art under 35 USC §103(a)/(c). More specifically, Cantantore was filed prior to, but was granted after the original filing date of the instant application, and thus would otherwise qualify as prior art only under 35 USC §102(e). However, Cantantore and the instant invention are commonly owned by Bayer, and thus Cantantore is disqualified under 35 USC §103(c) as prior art for purposes of asserting a 35 USC §103(a) rejection. Note, the instant application was filed as a CPA after the November 29, 1999. (See MPEP §706.02(l)(1)).

Accordingly, for at least this reason, , Applicants respectfully request that the §103 rejection of claims 1-12 be withdrawn.

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Conclusion

In view of the above remarks, Applicants respectfully submit that the application is in condition for allowance. Reconsideration and withdrawal of the Examiner's rejections is respectfully requested and allowance of all pending claims is respectfully submitted.

If any outstanding issues remain, or if the Examiner has any suggestions for expediting allowance of this application, the Examiner is invited to contact the undersigned at the telephone number below.

The Examiner's consideration of this matter is gratefully acknowledged.

Respectfully submitted,

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Date: October 7, 2003   By: _____

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